EXHIBIT C

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
THIS DOCUMENT RELATES TO PLAINTIFFS: Christine Wiltgen Case No. 2:12-cv-01216 Laura Waynick Case No. 2:12-cv-01151 Denise Burkhart Case No. 2:12-cv-01023 Debra A. and Donald Schnering Case No. 2:12-cv-01071 Karen Bollinger Case No. 2:12-cv-01215	

GENERAL DEPOSITION OF
KIMBERLY KENTON, M.D.
March 25, 2016
Chicago, Illinois

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The deposition of KIMBERLY KENTON, M.D., called by the Plaintiffs for examination, taken pursuant to the Federal Rules of Civil Procedure of the United States District Courts pertaining to the taking of depositions, taken before CORINNE T. MARUT, C.S.R. No. 84-1968, Registered Professional Reporter and a Certified Shorthand Reporter of the State of Illinois, at the offices of Drinker Biddle & Reath LLP, Suite 3700, 191 North Wacker Drive, Chicago, Illinois, on March 25, 2016, commencing at 1:51 p.m.

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REPORTED BY: CORINNE T. MARUT, C.S.R. No. 84-1968

A. Yes. Sorry. Yes, if I recall.

Q. We don't have you on video today. I just have to wait until you give an affirmative answer.

A. Yeah, I apologize.

Q. Now, you use the retropubic device in the majority of your patients instead of the transobturator procedure, correct?

A. I do.

Q. And why is that?

A. Several reasons, the first being I think that when you look -- although the long-term outcome data, you can't declare them equivalent or not equivalent in our own study, there was a slightly higher cure of stress incontinence with the retropubic.

And I think that that's consistent with what we understand, what we think we understand about incontinence procedures is the more obstructive they are, the more likely they are to cure stress incontinence and possibly induce a little bit more urgency. So...

Q. Is there any other reason that you use the retropubic over the transobturator?

want to know if you're aware of anything. I think what you're telling me is you don't know of any studies that have been done like that and you don't know how such a study would even be conducted. Is that fair enough?

MR. ROSENBLATT: Object to form.

BY THE WITNESS:

A. I wouldn't know how to conduct that study.

BY MS. FITZPATRICK:

Q. Okay. Do you know of any clinical trials that have been done to assess specifically the safety of the TVT-O device made by Ethicon?

A. So, a clinical trial by definition is comparative. You can't really do a randomized controlled trial to look at safety because, fortunately, most of these complications are rare. So, most of the clinical trials are designed to look at efficacy with safety endpoints.

And then it brings us to the systematic reviews and the meta-analyses where we use, fortunately, validated outcome measures that we can try to compile those to more objectively look at safety.

rare?

A. Sure. I mean, I'm not sure I walk around with a clear cutoff of what rare is.

Q. Okay. But somewhere in that neighborhood?

A. Yeah.

Q. Okay. You know, though, that there are complications that are unique to the helical trocars that are used with the TVT-O versus the trocars that are used with the TVT Retropubic, correct?

A. So, can we just like upfront -- I think that there are unique complications associated with the transobturator route of sling placement that differ from the retropubic. I don't know if it's from the trocar or the sling or if I just took a surgical instrument and put it through that space it would be different. Do you understand the difference in those?

Q. Okay.

A. Let's just like so we don't have to keep going back to that thing. I think that there are differences in complications with the two procedures, whether it's the trocar, whether it's

the method of passage.

I mean, I could theoretically say that I could just take a surgical instrument and still pass it like how we used to with old-fashioned retropubic slings. That's exactly how we pass the TVT. It's not that different.

If I took a uterine packing forceps and pass it through the transobturator space, I think we would see similar complications that are unique to passing something through the transobturator space.

Q. Okay. So, let's --

A. It's the route of access more than I think it's the device, like that particular trocar.

Q. So, with -- just let me see if I have got this right.

So, what you're saying with the TV -- some of the unique complications, and we can get to what those are, but those unique complications with the obturator procedure, you think are more related to the route of access through the obturator space than the actual trocar itself causing the injury?

A. Correct.

Q. Is that -- okay.

Q. Okay. So, I think that what we had discussed was that --

A. I would be retired and not sitting here if I knew how to tension it exactly right for every woman.

Q. Okay. And, so, that's something that is inherent in the transobturator midurethral slings as well, the difficulty in getting consistent tensioning from patient to patient to patient to patient, correct?

A. Yeah. I think that -- I think -- I think what I meant to say or what I implied or wanted to say was it's not inherent.

So, you don't -- you are trying to compensate for a nerve and a muscle that don't work. How sick your nerve and muscle are may be different, if you have incontinence, may be different than how sick mine is.

I think that one of the limitations of all continence procedures is how do I decide how to tight to make it for you that you can void freely and not have stress incontinence. It may be different for me.

And I think that that's uniform across

Q. And the TVT-O is designed by Ethicon to be implanted surgically through the obturator space, correct?

A. Correct.

Q. And sometimes that surgical placement can cause complications that are unique to the obturator midurethral slings, correct?

A. Correct. I can agree with all that.

Q. And in addition to the surgical procedure that you use through the obturator space, there is a piece of mesh that's used, correct?

A. Yes.

Q. And that mesh is left in the obturator space when you're done with your surgery, correct?

A. Correct.

Q. And that mesh in the whole pelvic region, that can cause certain complications for women, correct?

A. Correct.

Q. And, so, it seems to me that what this study is suggesting is that the complications that are related to the TVT-O either are related to the surgical route of implantation or the use of mesh.

And all I am asking is do you agree with

me that those are two different --

A. Yes.

Q. Okay. Now, are you aware of what technique was used to implant the TVT-O devices that were at issue in Exhibit 6?

A. I would have to look back through the paper.

Q. So, if you can quickly look through this paper, I would appreciate it, because the surgical technique that was used in this procedure was not the surgical technique that was or that is recommended by J & J/Ethicon, correct?

Instead, it's a surgical technique that was modified as originally described by Dr. de Leval?

MR. ROSENBLATT: Object to form.

BY THE WITNESS:

A. No. I would have to -- I mean, I would have to read that and I would have to read the paper.

BY MS. FITZPATRICK:

Q. This is your paper, right, this is the one that you relied on?

A. Well, I read the literature all the

fulfilled the promise shown in the short-term and medium-term. Therefore, it is imperative that more careful long-term evaluation of TVT-O techniques is carried out with the focus on complications and durability. Larger studies with longer follow-up periods should identify risk factors for failure and thus lead to better preoperative consultation."

Do you see that?

A. Yes.

Q. Do you agree with that comment?

A. So, which part of it? There is like several comments there. Can we just figure out what you want me to agree or disagree?

Q. Sure. Do you think it's imperative that more careful long-term evaluation of TVT-O techniques is carried out with the focus on complications and durability?

A. I think that, yes, that all obturators -- all surgical procedures in general.

Q. Do you believe that for the TVT-O technique specifically that there should be more careful long-term evaluation of its technique with the focus on complications and durability?

A. I think that we actually have good

medium-term data at about five years. But, yes, we need to follow women for longer periods of time.

Q. Okay. And do you agree with this paper that larger studies with longer follow-up periods should identify risk factors for failure and then -- and thus lead to better preoperative consultation?

A. I don't think that -- I think it's a nice statement, but I don't think that you're going to get longer studies that are well done with longer term follow-up. I think it's going to have to be systematic reviews and meta-analyses that are trying to compile these things. You can't get women to be in studies for 10, 20 years. It's hard to do.

Q. Well, but a systematic review and a meta-analysis isn't going to tell you what the complications are going to look like at 8 or 10 or 15 or 20 years, correct?

A. Well, they will. When we get cohorts and RCT data out far enough, it will help us with that.

Q. So, then what I guess I'm trying to understand is you just told me that it's difficult

know which complications. Yeah.

Q. If the complication --

A. That's what I said.

Q. -- was included in Dr. Culligan's paper, it would be included somewhere in Table 3 associated with a pubovaginal sling?

A. I -- I think so, yes.

Q. Okay. Are autologous fascial slings an appropriate alternative to the transobturator -- TVT-O transobturator sling?

A. Yes.

Q. Is the Burch procedure an acceptable appropriate alternative to the TVT-O transobturator sling?

A. Yes.

Q. And neither of those procedures produces the same rate of groin pain or leg pain as does the TVT-O procedure, correct?

A. Correct.

MR. ROSENBLATT: Object to form.

BY THE WITNESS:

A. They have a different type of risk/benefit ratio.

BY MS. FITZPATRICK:

more --

Q. Yeah, I think if you are looking at the adverse events.

A. Okay. I am looking at the wrong page. I'm in "Warnings and Precautions."

Q. Or "Adverse Reactions."

A. Are you in "Warnings and Precautions"?

Q. No, I'm on "Adverse Reactions."

A. Much smaller list.

Q. I will admit some of this is extraordinarily hard to read.

A. Much smaller list. "Adverse Reactions."

Q. The adverse reactions are the same for the TVT and the TVT-O, correct?

A. Yes.

Q. So, there is nothing that in those -- that "Adverse Reactions" section that can alert the doctor to what you know and have testified about the difference in the risk profiles for these particular products?

A. Not in the "Adverse Reactions" portion. They're the same. But there is other information that can alert them.

Q. In the IFU? Tell me what's different.

A. "Transient leg pain lasting 24 to 48 hours." I'm pretty sure that isn't in the retropubic one. I mean, some are common sense.

Q. There is nothing in the obturator one about chronic leg pain, correct?

A. Not that -- is this -- yeah, there is.

Q. One slightly easier.

A. Not chronic, no.

Q. Chronic, yes. That's what I was asking.

There is nothing about --

A. Very short time.

Q. -- groin pain, but it's the transient one. Okay.

Anything else?

A. That's the only thing that like popped. Like in this other one they are talking about postoperative restrictions.

Q. I think that's in both of them.

A. Oh, yeah. It's higher up on the other one.

So, it seems that that's the primary difference.

Q. So, apart from the reference to the transient leg pain -- hang on. The brains of the